

## REMARKS

### *Priority Claim*

Applicant requests that the Office acknowledge the claim of priority under 35 USC Section 119(e). The present application is a National Phase of PCT Application No. PCT/IL2004/000965, filed on 10/24/2004 which claims benefit of US Provisional Application No. 60/513,696, filed on 10/24/2003.

### *Drawings*

Applicant requests that the Office to acknowledge the Drawing Office review of the drawings as noted in the Office Action Summary.

### *Specification*

The Office objects to the amendment made to the specification in the previous Response as containing new subject matter. The applicant respectfully disagrees.

As illustrated in Fig. 2, narrow lumen 50 is indeed shown as an internal bore. Flexible tube 54 is coupled to the lumen with its proximate end. The replacement of proximal and distal merely made the description consistent with the figure. Similarly, it is clearly supported that the light does not pass axially through the lumen 50. "reflected light beams 64, reflected from the sector 46 on the eye are guided by total internal reflection along the walls of the LPCT 48 and further propagate through the light guiding device 56 impinging on a light detector 72. Reflector 58 blocks light reflected from the eye from reaching light detector 72 directly through the lumen 50. . . ." (p. 7, ll. 17-21) Similarly, Fig. 2 illustrates the concentration of the light prior to the striking the detector.

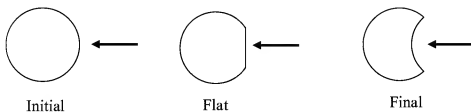
The applicant therefore requests that the Office withdraw its Objection to the specification.

**Claims Rejections - 35 USC §101**

The Examiner has rejected claims 1-4, 6, 7, 10 and 11 under 35 USC § 101 on the grounds that the disclosed invention is inoperative and therefore lacks utility. The Examiner avers that the newly added claim limitation that light is prevented from reaching the sensor when the body is flattened results in the device being unable to record changes in reflected light as the body is flattened to determine pressure.

The Examiner further states that as it is impossible to determine the pressure of the eye without monitoring changes in the reflected light as pressure is applied to the body causing the body to be flattened, it was not possible to apply significant prior art.

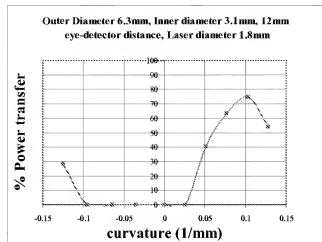
Applicant respectfully refutes this objection. When pressure is applied to the eye as shown schematically below by the arrows, the cornea distorts from a generally convex contour to a generally concave contour as shown below:



In the initial position, light depicted by the arrow is reflected through the walls of the tonometer and detected by the sensor; in the final position light is also reflected through the walls of the tonometer and detected by the sensor. Only in the instantaneous moment when the cornea is completely flat as shown schematically in the middle view is there no light reflected through the walls of the tonometer and detected. Therefore during the act of applying a pressure pulse to the eye, the eye gradually changes shape from one initial extreme to an opposite final extreme and all this time light is reflected and detected. Only at the very instant where the eye is flat is no light reflected through the walls of the tonometer and detected by the sensor.

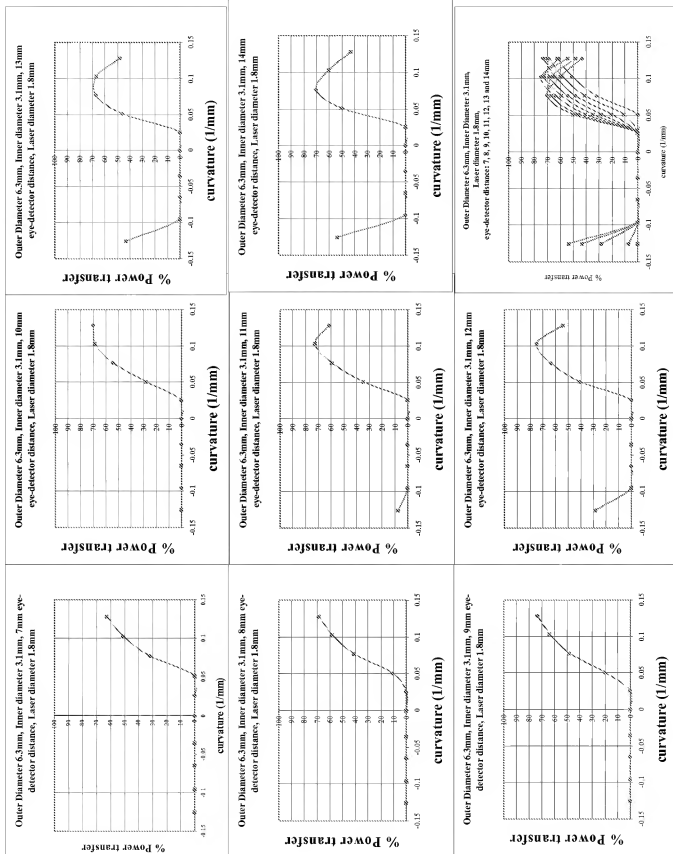
Thus, as far as the detector is concerned, it does detect a time-varying signal that commences with the application of a pressure pulse, drops to a minimum at the position of appplanation (when the cornea is flat) and then rises to a maximum when the cornea is fully depressed.

The shape of the resulting signal detected by the sensor is therefore as show below:



The above figure shows simulated light intensity (power) as a function of the curvature of the eye for a given distance of the tonometer tube from the cornea consequent to light passing through the tube of the tonometer, via the eye and through the walls of the tube and finally to the detector.

The striking effect that can be observed is the steep slope at which the graph rises from the x-axis close to zero curvature. It has been found that this remains true over a significant range of distances. For the sake of completeness, we show below a range of simulations for tonometer-to-eye distances of 7, 8, 10, 11, 13 and 14 mm all showing the same phenomenon, namely a sharp rise of measured light power at close to zero curvature corresponding to appplanation of the cornea.



**Claims Rejections - 35 USC §112 First Paragraph**

The Office rejects claims 1-4, 6, 7, 10 and 11 as failing to comply with the written description requirement. Specifically, the Office alleges that the claimed invention recites “a method and device wherein a light detector does not receive light reflected from the body when in a flattened configuration wherein changes in reflected light determines pressure of the body”. The applicant respectfully submits that, as is clear from the specification as filed, unlike known devices, the tonometer according to the claimed invention provides a sharp and detectable indication of the instant of applanation; and furthermore that this detection is fairly insensitive to the tonometer-to-eye distance unlike conventional devices which must be maintained in close and fixed relationship to the eye.

The fact that the detected light intensity is essentially zero at the instant of applanation is thus hardly a deficiency as apparently understood by the Examiner.

In para. 2, the Examiner has rejected claims 1-4, 6, 7, 10 and 11 under 35 USC § 112, first paragraph on the alleged grounds that amended claims are not supported by the description as originally filed. The Examiner contends that “applicant’s disclosed invention as originally filed discloses wherein light is detected by the detector prior to and during a flattened configuration and wherein the changes in the refracted [sic] light resulting from a pressure deformation is used to calculate a pressure of the body.” He then refers us to the description on page 8, line 6 through page 9, line 16 which states that ‘A convex surface of the undistorted cornea implies a larger effective area, which reflects light back towards face 52 of Fig. 2. A planar surface has smaller effective area which reflects this illuminating light towards face 52 of LPCT 48, and therefore correlates with a lower light intensity reflected.’”

It is respectfully noted that nowhere in the application is it stated that light is detected by the detector prior to **and during** a flattened configuration, although of course the detector is continually

operative to detect reflected light during the complete pressure cycle. We can only assume therefore that the Examiner is paraphrasing the description based on his apparent misunderstanding.

But it is true, of course, that light is reflected from the cornea even when it is flat. However, this light will be reflected **axially** and therefore will not strike the walls of the light projecting and a collecting tube (LPCT). As noted on page 7, lines 17-22:

The wall of LPCT 48 is transparent in the spectral range of the light beam and has a suitable index of refraction. Reflected light beams 64, reflected from the sector 46 on the eye, **are guided by total internal reflection along the walls of LPCT 48 and further propagate through the light guiding device 56 impinging on a light detector 72. Reflector 58 blocks light reflected from the eye from reaching light detector 72 directly through the lumen 50.** Light detector 72 is attached to the distal face of light guide 56 normal to the axis of LPCT 48. [Emphasis added]

This feature is crucial to a proper understanding of the invention since what it teaches is that the light that is detected is only that light that is totally internally reflected through the walls of the LPCT. Axially-reflected light that passes through the lumen is blocked. When the cornea is flat at the moment of applanation, light is reflected axially and so never reaches the walls of the LPCT: it is therefore not detected.

Therefore, there is no contradiction between what is now claimed and what is originally disclosed. The applicant therefor respectfully submits that the claimed invention is enabled by the written description and respectfully requests that the Office withdraw its rejection of claims 1-4, 6, 7, 10 and 11.

#### **Claim Rejections – 35 USC § 103**

In para. 3, the Examiner has rejected claims 1-4, 6, 7, 10 and 11 under 35 USC § 112, first paragraph as allegedly not complying with the enablement requirement. It is respectfully submitted that this objection is rendered moot in the light of what is stated above.

Favorable reconsideration and allowance are accordingly solicited.

Applicant believes the above amendments and remarks to be fully responsive to the Office Action, thereby placing this application in condition for allowance. No new matter is added. Applicant requests speedy reconsideration, and further requests that Examiner contact its attorney by telephone, facsimile, or email for quickest resolution, if there are any remaining issues.

Respectfully submitted,

**/Andrew P. Cernota, Reg. No. 52,711/**

Cus. No. 24222  
Vern Maine & Associates  
547 Amherst St., 3<sup>rd</sup> Floor  
Nashua, NH 03063-4000  
Tel. No. (603) 886-6100, Fax. No. (603) 886-4796  
patents@vernmaine.com

Vernon C. Maine, Reg. No. 37,389  
Andrew P. Cernota, Reg. No. 52,711  
David A. Rardin, Reg. No. 52,153  
Douglas P. Burum, Reg. No. 65,019  
Attorneys/Agents for Applicant